IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. AND TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively, "Plaintiffs"), by way of Complaint against Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (collectively, "Teva"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Reissue Patent No. RE48,059 ("the RE059 patent"), arising under the United States patent laws, Title 35, United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Teva's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to engage in the commercial manufacture, use or sale of generic pharmaceutical products before the expiration of the RE'059 patent.

THE PARTIES

2. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

3. Lundbeck is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Otsuka has granted Lundbeck an exclusive license to the 'RE059 patent.

4. Otsuka and Lundbeck are engaged in the business of researching, developing and bringing to market innovative pharmaceutical products.

5. Upon information and belief, Teva USA is a corporation organized under the laws of Delaware and its principal place of business is located at 400 Interpace Parkway, Parsippany, NJ 07054.

6. Upon information and belief, Teva USA is a wholly owned subsidiary of Teva Ltd. https://www.tevagenerics.com/about-teva-generics/who-we-are (Teva USA Generics Profile, accessed Oct. 20, 2020).

7. Upon information and belief, Teva Ltd. is a corporation organized under the laws of Israel and its principal place of business is located at 5 Basel Street, Petach Tikva, 49131, Israel.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Teva USA. Upon information and belief, Teva USA is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Teva USA directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Teva USA purposefully has conducted

and continues to conduct business in this judicial district, and this judicial district is a likely destination of Teva's generic products.

10. Upon information and belief, Teva USA admits it is responsible for "1/10 prescriptions in the US," is "leading with 100 pending first-to-file ANDAs in the U.S.," has "270 product registrations pending FDA approval" and had "1000 generic launches globally in 2019." https://www.tevausa.com/About-Teva/article-pages/facts-and-figures#item(281738) (Teva Facts & Figures, accessed Oct. 21, 2020); *see also* https://www.tevausa.com/About-Teva/article-pages/facts-and-figures#item(281743) (Facts & Figures, accessed Oct. 21, 2020) ("Teva is the leading generic drug company in the United States[.]").

11. Upon information and belief, Teva USA has active pharmacy wholesale licenses in the state of Delaware with the license numbers A4-0001468 and A4-0001447 and active controlled substances distributor/manufacturer licenses in the state of Delaware with the license numbers DM-0007115 and DM-0006546.

12. This Court has personal jurisdiction over Teva Ltd. Upon information and belief, Teva Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Teva Ltd. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Teva Ltd. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Teva's generic products.

13. Upon information and belief, Teva Ltd. admits it is "the world's leading provider of generic pharmaceuticals" and that it "produces 120 billion tablets and capsules a year in 70 pharmaceutical API facilities around the world." https://www.tevapharm.com/our_products/g

eneric_products (Teva Ltd. Generic Products Profile, accessed Oct. 12, 2019). Upon information and belief, Teva Ltd. admits it has "more than 3,500 medicines" and "[t]he most extensive [generic] product portfolio in the industry: 1 in 9 generic prescriptions in the US are filled with Teva products[.]" https://www.tevapharm.com/about/profile/who_we_are (accessed Oct. 15, 2019).

14. Upon information and belief, Teva Ltd. is the holder of FDA Drug Master File No. 33450 for brexpiprazole.

15. Upon information and belief, Teva USA and Teva Ltd. hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

16. Teva's ANDA filing regarding the RE'059 patent relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Teva's intent to market and sell Teva's generic products in this judicial district.

17. Teva has taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—which, upon information and belief, will be purposefully directed at the District of Delaware and elsewhere throughout the United States. Upon information and belief, Teva intends to direct sales of its generic drugs in this judicial district, among other places, once Teva receives the requested FDA approval to market its generic products. Upon information and belief, Teva will engage in marketing of its proposed generic products in Delaware upon approval of its ANDA.

18. Upon information and belief, Teva has thus been, and continues to be, the prime actor in drafting, submission, approval and maintenance of ANDA No. 213692.

19. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Teva USA is incorporated in the state of Delaware.

20. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Teva Ltd. is incorporated in Israel and may be sued in any jurisdiction.

FACTUAL BACKGROUND

The NDA

21. Otsuka is the holder of New Drug Application ("NDA") No. 205422 for REXULTI® (brexpiprazole) Tablets in 0.25, 0.5, 1, 2, 3 and 4 mg dosage forms ("REXULTI® Tablets").

22. The FDA approved NDA No. 205422 on July 10, 2015.

23. REXULTI® Tablets are prescription drugs approved for the adjunctive treatment of major depressive disorder and the treatment of schizophrenia. Brexpiprazole is the active ingredient in REXULTI® Tablets.

The Patent In Suit

24. The United States Patent and Trademark Office ("the PTO") issued U.S. Patent No. 7,888,362 ("the '362 patent") on February 15, 2011, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders."

25. The PTO reissued the '362 patent as the RE'059 patent on June 23, 2020. A true and correct copy of the RE'059 patent is attached as Exhibit A.

26. As the reissue of the '362 patent, Otsuka is the owner of the RE'059 patent through assignment as recorded by the PTO for the '362 patent at Reel 048501, Frame 0122; Reel 021939, Frame 0746 and Reel 048501, Frame 0166.

27. Pursuant to 35 U.S.C. § 251, the RE'059 patent issued for the unexpired term of the '362 patent, which would have expired on April 12, 2026, by virtue of a terminal disclaimer filed in the PTO that disclaimed 317 days of patent term adjustment granted to the '362 patent under 35 U.S.C. § 154(b). A true and correct copy of the terminal disclaimer is attached as Exhibit B.

28. Otsuka filed a Submission Pursuant to 37 C.F.R. § 1.765 for Patent Term Extension Application Under 35 U.S.C. § 156 and Response to Notice of Final Determination, requesting an extension under 35 U.S.C. § 156(c) of 986 days for the '362 patent. After the RE'059 patent issued, Otsuka filed a Petition Under 37 C.F.R. § 1.182 to Move Patent Term Extension Application from U.S. Patent No. 7,888,362 to RE 48,059, which was granted on October 6, 2020. Accordingly, the RE'059 patent will expire on December 23, 2028, based on the 986 days of Patent Term Extension under 35 U.S.C. § 156(c).

29. The RE'059 patent is listed in Approved Drug Products With Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

The ANDA

30. Upon information and belief, Teva filed ANDA No. 213692 with the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the commercial manufacture, use or sale in the United States of brexpiprazole tablets, 0.25, 0.5, 1, 2, 3, and 4 mg ("Teva's generic products"), which are generic versions of Otsuka's REXULTI® (brexpiprazole) Tablets.

31. Otsuka received a letter sent by Teva USA, dated September 6, 2019, purporting to be a "Notice of ANDA No. 213692" ("Teva's September 6, 2019, First Notice Letter") pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Teva's

September 6, 2019, First Notice Letter notified Otsuka that Teva had filed ANDA No. 213692, seeking approval to engage in the commercial manufacture, use or sale of Teva's generic products before the expiration of the '362 patent and U.S. Patent Nos. 8,349,840; 8,618,109; 9,939,637 and 10,307,419. U.S. Patent No. 9,939,637, entitled "Virtual Image Display Device, Head-Up Display System, and Vehicle," is not listed in the Orange Book for Otsuka's REXULTI® Tablets.

32. Otsuka received a second letter sent by Teva USA, dated September 17, 2019 ("Teva's September 17, 2019, Second Notice Letter"), notifying Otsuka that Teva's September 17, 2019, Second Notice Letter was being provided to Otsuka "to merely correct a typographical error with regard to U.S. Patent No. 9,839,637, which was previously referred to as U.S. Patent No. 9,939,637." Teva's September 17, 2019, Second Notice Letter further notified Otsuka that Teva had filed ANDA No. 213692, seeking approval to engage in the commercial manufacture, use or sale of Teva's generic products before the expiration of the '362 patent and U.S. Patent Nos. 8,349,840 ("the '840 patent"); 8,618,109 ("the '109 patent"); 9,839,637 ("the '637 patent") and 10,307,419 ("the '419 patent").

33. In response to Teva's September 6, 2019, First Notice Letter and Teva's September 17, 2019, Second Notice Letter (collectively, "Teva's 2019 Notice Letters"), Plaintiffs previously filed a separate action in this Court against Teva for patent infringement, which included counts of infringement of the '362, '840, '109, '637 and '419 patents. *See Otsuka Pharmaceutical Co., Ltd., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, C.A. No. 19-1955-LPS. Therein, Plaintiffs reserved all rights and continue to reserve all rights to challenge the sufficiency of Teva's 2019 Notice Letters and ANDA No. 213692. *See id.* at D.I. 1, ¶ 48.

34. On June 23, 2020, the PTO issued the RE'059 patent as a reissue of the '362 patent. Plaintiffs timely notified the FDA and the RE'059 patent was listed in the Orange Book for REXULTI®.

35. Upon information and belief, ANDA No. 213692 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification"), alleging that the claims of the RE'059 patent are invalid, unenforceable and/or would not be infringed by the commercial manufacture, use, sale, offer for sale and/or importation of Teva's generic products.

36. Otsuka received a third notice letter sent by Teva USA, dated September 10, 2020, purporting to be a "Notice of ANDA No. 213692" ("Teva's September 10, 2020, Third Notice Letter"), pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Teva's September 10, 2020, Third Notice Letter notified Otsuka that Teva had filed ANDA No. 213692, seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation in the United States of Teva's generic products before the expiration of the RE'059 patent.

37. Plaintiffs commenced this action within 45 days of receiving Teva's September 10, 2020, Third Notice Letter.

COUNT I

(INFRINGEMENT OF THE RE'059 PATENT)

38. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

39. Upon information and belief, Teva filed ANDA No. 213692 seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the RE'059 patent.

40. Upon information and belief, Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the RE'059 patent are invalid, unenforceable and/or not infringed.

41. Upon information and belief, in its ANDA No. 213692, Teva has represented to the FDA that Teva's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

42. Teva has actual knowledge of Otsuka's RE'059 patent, as evidenced by Teva's September 10, 2020, Third Notice Letter.

43. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed one or more claims of the RE'059 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213692, seeking approval to commercially manufacture, use, import, offer to sell or sell Teva's generic products before the expiration date of the RE'059 patent.

44. Upon information and belief, if ANDA No. 213692 is approved, Teva intends to and will offer to sell, sell and/or import in the United States Teva's generic products.

45. Upon information and belief, if ANDA No. 213692 is approved, Teva will infringe one or more claims of the RE'059 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Teva's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213692 shall be no earlier than the expiration of the RE'059 patent and any additional periods of exclusivity.

46. Upon information and belief, Teva's actions relating to Teva's ANDA No. 213692 complained of herein were done by and for the benefit of Teva.

47. Plaintiffs will be irreparably harmed by Teva's infringing activities unless this Court enjoins those activities.

48. Plaintiffs do not have an adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the RE'059 patent through Teva's submission of ANDA No. 213692 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the RE'059 patent;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Teva's making, using, offering to sell, selling or importing of Teva's generic products before the expiration of the RE'059 patent will infringe, actively induce infringement and/or contribute to the infringement of the RE'059 patent under 35 U.S.C. § 271(a), (b) and/or (c);

C. The issuance of an order that the effective date of any FDA approval of Teva's generic products shall be no earlier than the expiration date of the RE'059 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from commercially manufacturing, using, offering for sale or selling Teva's generic products within the United States, or importing Teva's generic products into the United States, until the expiration of the RE'059 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from seeking, obtaining or maintaining approval of the ANDA until the expiration of the RE'059 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

G. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

H. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

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